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10/777,471	02/12/2004	Adnan M.M. Mjalli	41305-296607	2244

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/777,471	Applicant(s) MJALLI ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 46-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

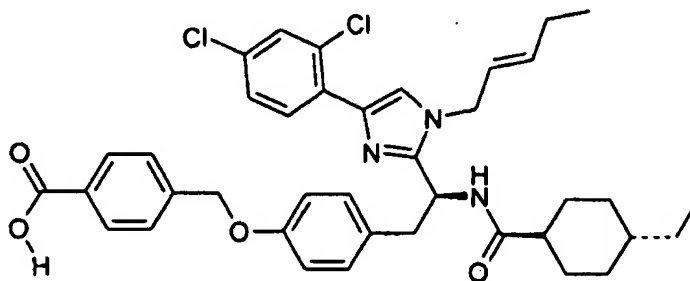
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DETAILED ACTION

Claims 1-62 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III (claims 1-45), and the species of Example 146 found on pages 185-186 of the instant specification (reproduced below), in the reply filed on October 27, 2006 is acknowledged.

Example 146

4-(4-{2-[4-(2,4-Dichloro-phenyl)-(E)-1-pent-2-enyl-1H-imidazol-2-yl]- (2S)-2- [(trans-4-ethyl-cyclohexanecarbonyl)-amino]-ethyl}-phenoxy-methyl)-benzoic acid

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The traversal is on the ground(s) that there would not be a serious burden on the Examiner if restriction were not required because a search of the prior art relevant to the claims of Group III would provide the relevant prior art for Groups I, II, IV, V and VI.

This is not found persuasive because separate search considerations are involved for each of the outlined groups in the Restriction Requirement. Further, a search of the products of Group III would not necessarily reveal references relevant to the inventions of Groups I, II, IV, V and VI. Also, the examination is also burdensome because of the 20 page IDS filed by Applicant on November 15, 2004. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application were unrestricted.

Additionally, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims

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commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant's compound genus of Claim 1 has a number of variables, including a multitude of definitions, and their permutations and combinations result in a vast number of compounds that are generically claimed. In an attempt to examine the full scope of elected Group III, over 2700 CA Registry numbers were recovered on one database search alone. Additionally, and as stated

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above, the examination is also arduous because of the 20 page IDS filed by Applicant on November 15, 2004. Therefore, the instant application will be examined according to MPEP 803.02.

The claims within elected Group III and the IDS have been examined to the extent that they are readable on the elected species of Example 146. Since no prior art was found on the elected species, the examination was expanded within elected Group III until art was found, in which case, the examination stopped and art has been applied against the claims. Note, M.P.E.P. § 803.02. The subject matter of the expanded search (inclusive of the elected species of Example 146) is as follows:

W is $N(R_4)$;

X is $-C(O)-$;

Ar₁ is an optionally substituted phenyl;

Ar₂ is an optionally substituted phenylene; and

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all other variables are as defined.

The claims that are embraced by the subject matter of the expanded search are claims 1-45.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by the above indicated expanded search and Claims 46-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 27, 2006.

Information Disclosure Statement

The Examiner has considered the 20 page Information Disclosure Statement filed on November 15, 2004.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 33-35, 38 and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,

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3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

Applicant is claiming compositions for treating numerous diseases and disorders by administering a compound of formula (I). See, for example, instant claim 38. Additionally, claim 30 lists additional therapeutic agents but some of these agents are not adequately described in the instant specification (i.e., GK activators, GLP-1 mimetics, insulin mimetics, fibrates, etc.). From the reading of the specification, it appears that Applicants are asserting that the embraced compounds, because of their mode of action which involves the inhibition of protein

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tyrosine phosphatases (PTPases), would be useful for treating numerous diseases and disorders such as cancer, AIDS, Alzheimer's disease, autoimmune diseases, infectious diseases, etc. The instant specification teaches that "treating" embraces curing and preventing the onset of a disease or disorder (page 241).

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that cancer therapy, for example, remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, Vol. 286, October 15, 1999, pages 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, to maximize efficacy and minimize toxicity. Cancer classification has been based primarily on morphological appearance of

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the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al., Science, Vol. 286, October 15, 1999, pages 531-537). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Additionally, inflammation is a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people

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who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can be used to treat, cure or prevent the onset of all of the diseases embraced by the claims is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating, curing or preventing the onset of any or all conditions by administering the instant claimed compounds.

The breadth of the claims

The breadth of the claims is treating, curing or preventing the onset of all of the diseases and disorders generically embraced in the claim language.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological

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activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of improper Markush language when "comprises" or "comprising" is used to define a variable such as in the definition of variables a and b. See claims 11 and 13 for same. Applicant is required to check all claims for this issue.

Claim 1 is indefinite because there are two different definitions of the X variable and the Y variable.

In claim 21, an "and" is needed before the last compound listed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-10, 12, 13, 16, 18, 20 and 22-45 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by:

a) Thurieau et al. {WO 2002/10140} - see, for instance, Example 47 on page 134;

b) Mjalli {WO 2000/23487} - see, for instance, Compound 7 on page 30;

c) Gordon {WO 99/65942} - see, for instance, the compound of Step j on page 50;

d) Thurieau et al. {WO 99/64401} - see, for instance, the compound of Example 33 on page 133; or

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e) Yatabe et al. {CA 129:95714, 1998} - see, for example, the compound of CA Registry No. 209525-71-3.

Each of the above cited prior art disclose at least one compound that is embraced by the instant claimed invention. Therefore, each of the cited prior art anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3 and 5-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurieau et al. {WO 2002/10140} and Thurieau et al. {WO 99/64401}, each taken alone or in combination with each other when similar utilities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims imidazole compounds. Thurieau et al. '140 (pages 2-6, 20, 21 and 23-25; and especially Example 47 on page 134) and Thurieau et al. '401 (pages 2-7, 20, 21 and 24-26; and especially Example 33 on page 133) each teach imidazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that

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the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, inflammation. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

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Allowable Subject Matter

The elected species of Example 146, found on pages 185-186 of the instant specification, is allowable over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

January 22, 2007